

**DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

3321. Misbranding of P. M. Massager. U. S. v. Herschell R. Coil (Wawasee Therapy Co.). Plea of nolo contendere. Fine of \$100, plus costs. (F. D. C. No. 29991. Sample No. 42868-K.)

INFORMATION FILED: November 7, 1950, Northern District of Indiana, against Herschell R. Coil, trading as the Wawasee Therapy Co., Syracuse, Ind.

ALLEGED SHIPMENT: On or about November 6, 1949, from the State of Indiana into the State of Illinois.

PRODUCT: Examination showed that the device was an 8-inch hard rubber tube with a soft rubber handle on one end and a small, soft rubber lobe on the other end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in circulars entitled "To Massage the Prostate through the Rectum" and "Prostate Sufferers," which accompanied the device, were false and misleading since the device would not be efficacious for the purposes represented. The statements represented and suggested that the device would be efficacious in the treatment of stiff joints, lack of ambition, tired listlessness, nervousness, aching legs, burning feet, and inability to relax due to continual tension; and that the device would be efficacious to restore virility.

Further misbranding, Section 502 (j), the device was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "a new instrument made for the sole purpose of enabling you to do this Massaging * * * It can be used gently or firmly according to the necessary requirements to remove the excess, irritating glairy liquid from the prostates * * * Five to 15 minutes twice a week gives amazing results," since such use of the device may result in perforation and rupture of the rectum, and such use by individuals with acute inflammation of the prostate may result in aggravation of the infective process.

DISPOSITION: January 8, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$100, plus costs.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS**

✓ 3322. Misbranding of Dexedrine Sulfate tablets and Benzedrine Sulfate tablets. U. S. v. John C. Booth (Booth Prescription Pharmacy). Plea of nolo contendere. Fine \$100 on each of first 2 counts of information; sentence suspended on remaining 2 counts. (F. D. C. No. 30012. Sample Nos. 75170-K, 75174-K, 75175-K, 75179-K.)

INFORMATION FILED: December 13, 1950, District of New Mexico, against John C. Booth, trading as the Booth Prescription Pharmacy, Portales, N. Mex.

INTERSTATE SHIPMENT: From the State of Texas into the State of New Mexico, of quantities of *Dexedrine Sulfate tablets* and *Benzedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about April 30 and May 1 and 2, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), 1 of the 3 lots of the repackaged *Dexedrine Sulfate tablets* and 1 lot of the repackaged *Benzedrine Sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: January 2, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$100 on each of the first 2 counts of the information and suspended the imposition of sentence on the remaining 2 counts.

✓3323. **Misbranding of Dexedrine Sulfate tablets and phenobarbital tablets.** U. S. v. Clay Blue and Carl F. Moore. Pleas of nolo contendere. Fine of \$100 against each individual on count 1; sentence suspended on remaining 3 counts of information. (F. D. C. No. 30011. Sample Nos. 49769-K to 49771-K, incl., 75177-K.)

INFORMATION FILED: December 13, 1950, District of New Mexico, against Clay Blue and Carl F. Moore, partners in the partnership of College Drug, at Portales, N. Mex.

INTERSTATE SHIPMENT: From the State of Texas into the State of New Mexico, of quantities of *Dexedrine Sulfate tablets* and *phenobarbital tablets*.

ALLEGED VIOLATION: On or about May 1 and 2, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: January 2, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 against each individual on the first count of the information and suspended the imposition of sentence on the remaining 3 counts.

3324. **Misbranding of Dexedrine Sulfate tablets and Seconal Sodium capsules.** U. S. v. Asher Smith (Asher Smith Pharmacy). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 29467. Sample Nos. 60222-K, 60223-K.)

INFORMATION FILED: November 3, 1950, Eastern District of Michigan, against Asher Smith, trading as the Asher Smith Pharmacy, Detroit, Mich.